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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,485	11/27/2001	Alexey G. Ryazanov	601-1-078DIV	1500

7590

08/12/2003

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EXAMINER

ANDRES, JANET L

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/994,485

Applicant(s)

RYAZANOV ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 51-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 27 May 2003 is acknowledged. Claims 51-59 are pending and under examination in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections/Objections Withdrawn***

2. The objection to the specification is withdrawn in response to Applicant's amendment.
3. The rejection of claims 51, 52, and 58 under 35 U.S.C. 101 is withdrawn in response to Applicant's amendment.

#### ***Claim Rejections Maintained/New Grounds of Rejection***

4. The rejection of claims 51 and 52 under 35 U.S.C. 102(b) as anticipated by Redpath et al. is maintained for reasons of record in the office action of paper no. 15.

Applicant has amended the claims to require that the antibody bind specifically to the disclosed proteins. Applicant argues that Redpath et al. does not teach either the particular eEF-2 kinases disclosed or the specifically binding antibodies claimed.

Applicant's arguments have been fully considered but have not been found to be persuasive. There is no definition of "specific binding" in the specification and no disclosure of antibodies that have such binding properties. "Specific binding" is generally taken to mean binding that is saturable and competable. The antibodies disclosed by Redpath et al. would react specifically with the disclosed sequences; they were, as stated previously, raised against peptides that are identical or nearly identical to sequences within the instantly disclosed polypeptides. Their binding to the proteins of SEQ ID Nos: 2 and 4 would thus be specific and not a fortuitous cross-reactivity; they would bind to the same sequences, or nearly the same sequences, against

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which they were raised. Thus Applicant's amendment does not distinguish what is claimed over the prior art; the antibodies disclosed by Redpath et al. would specifically bind to mouse and human eEF-2 kinase.

5. The rejection of claims 51 and 53-59 under 35 U.S.C. 103(a) as unpatentable over Redpath et al. in view of Harlow and Lane and of claims 51-59 as unpatentable over Ryazanov et al. in view of Harlow and Lane is maintained for reasons of record in the office action of paper no. 15.

Applicant has amended the claims to require that the antibody bind specifically to the disclosed proteins. Applicant argues that Redpath et al. does not disclose or suggest the particular kinases of the instant application and further does not disclose or suggest antibodies that specifically bind to them. Applicant further argues that Harlow and Lane provide only general direction. Applicant additionally argues, with respect to the *C. Elegans* protein of SEQ ID NO: 10 as disclosed by Redpath et al. and with respect to the rejections over Ryazanov et al., that "the knowledge of how to make antibodies in general does not make any and all antibodies to any known sequence obvious per se". Applicant additionally argues that Ryazanov et al. is not prior art, because each of the inventors was also an author of Ryazanov.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated above, the inclusion of the limitation "specifically binds" in the claims fails to distinguish them from what is known in the art. The antibodies taught by Redpath et al. would bind specifically to the mouse and human proteins. As stated previously, Harlow and Lane teach the claimed modifications of monoclonal antibodies, fragments, and labels and teaches uses for these modifications. Thus, it would be obvious to one of ordinary skill in the

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art, given the antibodies taught by Redpath et al., to make the modifications taught by Harlow and Lane, because Harlow and Lane teaches advantages to making these modifications.

Applicant's claims are not drawn to any particular antibody having any particular characteristics other than specific binding. Thus, what is required to render the claimed invention obvious are proteins that, when used to generate antibodies, would produce antibodies that meet the limitations of Applicant's claims, and the information and motivation to produce such antibodies. Such proteins are taught by Redpath et al. and Ryazanov et al. and both information sufficient to make antibodies meeting the limitations of the claims and the motivation for making such antibodies are taught by Harlow and Lane.

With respect to Applicant's statement that Ryazanov et al. cannot be considered prior art, MPEP § 2132.01 states: (emphasis added)

A prima facie case is made out under 35 U.S.C. 102(a) if, within 1 year of the filing date, the invention, or an obvious variant thereof, is described in a "printed publication" whose authorship differs in any way from the inventive entity unless it is stated within the publication itself that the publication is describing the applicant's work. In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982).

... Applicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under 35 U.S.C. 102(a). In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982) (discussed below). Therefore, where the applicant is one of the co-authors of a publication cited against his or her application, the publication may be removed as a reference by the filing of affidavits made out by the other authors establishing that the relevant portions of the publication originated with, or were obtained from, applicant. Such affidavits are called disclaiming affidavits. Ex parte Hirschler, 110 USPQ 384 (Bd. App. 1952). The rejection can also be overcome by submission of a specific declaration by the applicant establishing that the article is describing applicant's own work. In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). However, if there is evidence that the co-author has refused to disclaim inventorship and believes himself or herself to be an inventor, applicant's affidavit will not be enough to establish that applicant is the sole inventor and the rejection will stand. Ex parte Kroger, 219 USPQ 370 (Bd. Pat. App. & Int. 1982) (discussed below). It is also possible to overcome the rejection by adding the coauthors as inventors to the application if the requirements of 35 U.S.C. 116, third paragraph are met. In re Searles, 422 F.2d 431, 164 USPQ 623 (CCPA 1970).

6. The rejection of claim 59 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record in the office action of paper no. 12.

Applicant argues that the experimentation is not undue, that the direction is sufficient, that working examples are provided, that the nature of the invention, the guidance provided by the prior art, and the skill of those in the art is substantial, that the generation of antibodies is predictable, and that the breadth of the claim is commensurate with the skill of those in the art. Applicant argues that a diagnostic use is taught.

Applicant's arguments have been fully considered but have not been found to be persuasive. Generation of antibodies is, as is set forth above, routine. However, a "pharmaceutical composition" indicates that there is a therapeutic or diagnostic use for the antibodies. Applicant states only that "preliminary evidence suggests that eEF-2 kinase is upregulated in human cancers" (p. 6) and predicts (p. 29, cited previously) that "further experimentation will reveal a prognostic correlation between eEF-2 kinase levels and the prediction and/or progression of certain malignancies". No working examples for such a use are provided, and the development of a diagnostic or therapeutic use, unlike the generation of antibodies, is not a routine process with a predictably successful outcome. Applicant has provided no guidance beyond the mere suggestion that the kinase might be useful to diagnose some cancers. This is not adequate guidance as to the nature of the cancers that might be identified, and how levels of kinase might correlate with expression, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation.

What is provided is thus the idea for an invention, and the invitation to experiment to implement this invention, not the invention itself.

7. The rejection of claim 58 under 35 U.S.C. 112, second paragraph, as indefinite is maintained for reasons of record in the office action of paper no. 12.

Applicant has not addressed this rejection and it is therefore maintained.

8. Claims 51-59 are newly rejected under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of "specifically binds". Applicant has not defined this term and one of skill in the art would not know what degree of binding was considered to be specific.

**NO CLAIM IS ALLOWED.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
July 31, 2003

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
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